NOTICE OF ALLOWANCE

Continued Examination under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 31, 2011 has been entered.

Claim Status

This office action is in response to the papers filed on May 31, 2011 and July 27, 2011. Claims 1-25 and 34-37 are pending in this application. Claims 1 and 15 are amended and new claim 37 is added. The claim amendments have been reviewed and entered. During the interview on August 11, 2011 Applicant's representative Ms. Subramony authorized to cancel claim 37 via Examiner's amendments. No new matter has been introduced by the claim amendments. Applicant's arguments filed on May 31, 2011 and July 27, 2011 have been fully considered and are moot in view of the withdrawn rejections. Claims 1-25 and 34-36 are pending in this application and are allowed.

Information Disclosure Statement

The references submitted in the information disclosure statement (IDS) submitted by the Applicant on May 31, 2011 and July 15, 2011 has been considered by the Examiner. The cited references have been reviewed and the method steps of claim 1 as amended below are novel over the cited references in the IDS .

Declaration under 37 CFR 1.132

The declaration under 37 CFR 1.132 filed on July 27, 2011 is sufficient to overcome the rejection of claims 1-25 and 34-36 based upon the 35 USC 103(a) as being unpatentable over combination of references.

Interview summary

The Examiner contacted the Applicant's representative Ms. Subramony on July 20, 2011 to discuss the reference of Haukanes regarding the use of magnetic beads for nucleic acid and proteins from the sample and to suggest amendments to claim 1 for placing pending claims in better condition for allowance. The Examiner in consultation with primary Examiner Kapushoc suggested the step of simultaneously contacting the sample with a plurality of magnetic beads binding to the nucleic acids and proteins present in the sample, wherein the sample is not contacted with a chaotropic agent may place the pending claims in better condition for allowance. The Examiner further suggested due to the wide use of magnetic beads for isolating nucleic acids and proteins, to file a declaration as to why one having ordinary skill in the art would not

combine the art of the record as suggested by the Examiner in the final office action of January 28, 20011. In response Applicant has filed a supplemental response on July 27, 2011. The Examiner contacted the representative on August 10, 2011 to discuss the claim amendments and suggested that the novelty of the invention over the prior art of the record is the step of simultaneously contacting the magnetic beads and not using the chaotropic agent The Applicant's representative e-mailed the amendments on August 11, 2011 for discussion purpose only.

Applicant's representative and the Examiner discussed the claim amendments e-mailed by the representative on August 11, 2011. During the interview Applicant's representative authorized the claim amendments and any other corrections for minor typographical errors..

Amendment to the Specification

Please insert the heading “Brief Description of Drawings" in page 43 between lines 5 and 6 of specification filed on July 12, 2004. No new matter has been introduced by the amendments. The amendments to the specification were authorized by the Representative Ms. Subramony on September 14, 2011.

EXAMINER’S AMENDMENT

An examiner’s amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided

by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Applicant's representative Ms. Subramony on August 11, 2011.

Claims 1-25 and 34-36 have been renumbered as Claims 1-28 according to 37 C.F.R. 1.126 (see MPEP 608.01 (j) and 608.01 (n) IV).

Claims 26-33 and 37 are cancelled.

The claims are rewritten as follows.

1. A method of isolating nucleic acid and protein from each other in a single sample, said method comprising:

a) providing a sample that comprises nucleic acid components and protein components;

b) contacting the sample with a plurality of magnetic particulate solid supports comprising:

(i) contacting the sample of step b with a first magnetic particulate solid support under conditions wherein nucleic acid components bind to the first magnetic particulate solid supports in a sequence independent manner and the protein components remain substantially intact; and simultaneously

(ii) contacting the sample of step b with a second magnetic particulate solid support distinct from the first magnetic particulate solid support, under conditions wherein protein components contained in the sample bind to the second magnetic particulate solid support through a chromatographic interaction and the nucleic acid components remain substantially intact; and

c) separating the first magnetic particulate solid support to which are bound nucleic acid components and the second magnetic particulate solid supports to which are bound protein components from unbound components in the sample, thereby isolating nucleic acid components and protein components that are substantially intact; wherein the sample is not contacted with a chaotropic agent.

2. The method of claim 1, wherein the method comprises providing a sample that contains DNA and RNA components, and further comprises binding both DNA and RNA components to the first magnetic particulate solid support.

3. The method of claim 1, wherein the method comprises providing a sample that contains RNA components, and further comprises contacting the sample with a third magnetic particulate solid support, wherein the first, second and third magnetic particulate solid supports are distinct, and wherein RNA components bind to the third magnetic particulate solid support.

4. The method of claim 3, further comprising contacting the sample with the first magnetic particulate solid support and the third magnetic particulate solid support in separate steps.

5. The method of claim 1, wherein the method comprises isolating nucleic acid and protein components from the same sample.

6. The method of claim 1, wherein the method comprises providing a sample containing mRNA.

7. The method of claim 1, wherein the method comprises providing a sample containing genomic DNA.

8. The method of claim 1, wherein the method comprises isolating total RNA and/or the total DNA from the sample.

9. The method of claim 1, wherein the method comprises isolating the total nucleic acid component from the sample.

10. The method of claim 1, wherein the method comprises isolating the total protein component from the sample.

11. The method of claim 1, further comprising providing a sample selected from a food or allied product, and a clinical, environmental or biological sample.

12. The method of claim 1, further comprising subjecting the sample to a preliminary treatment step to free the nucleic acid and/or protein components from structures or entities in which they may be contained.

13. The method of claim 1, further comprising providing a sample that comprises one or more cell populations, and subjecting the sample to a cell isolation procedure prior to contacting said sample with said plurality of first and second magnetic particulate solid supports.

14. The method of claim 13, further comprising separately isolating one or more particular cell populations from the sample.

15. The method of claim 1 or claim 13, further comprising subjecting the sample, or a cell population isolated therefrom, to a cell lysis step prior to contacting said sample with said first magnetic solid particulate support, wherein the cell lysis step may be performed in the absence of a chaotropic agent.

16. The method of claim 15, further comprising subjecting the cell surface proteins of cells within or isolated from said sample to an *in vitro* modification procedure prior to the cell lysis step.

17. The method of claim 1, wherein the sample is not divided at any stage of the method.

18. The method of claim 1, further comprising conducting a cell isolation, lysis, or preliminary treatment step conducted prior to contacting the sample with the first magnetic particulate solid support, and dividing the sample after the cell isolation, lysis, and/or preliminary treatment step.

19. The method of claim 1, wherein said sample is contacted with said plurality of magnetic particulate solid supports sequentially or simultaneously.

20. The method of claim 19, wherein in a first step DNA is isolated from said sample, in a second step RNA is isolated from said sample and in a third step, protein is isolated from said sample, and wherein said steps may be performed in any order.

21. The method of claim 1, further comprising isolating DNA components on the first magnetic particulate solid support selected from supports carrying surface carboxyl or hydroxyl groups, silica or silica-based supports, and supports having a polyamine coated surface.

22. The method of claim 1, further comprising binding nucleic acid components from the sample to the plurality of first magnetic particulate solid support in the presence of a detergent.

23. The method claim 15, further comprising subjecting the sample to a cell lysis step, wherein cell lysis and nucleic acid binding to the first magnetic particulate solid support occur simultaneously or concomitantly.

24. The method of claim 3, further comprising isolating RNA components from the sample using an RNA-specified capture-probe carried by or attached to, or capable of binding to said first magnetic particulate solid support.

25. The method of claim 24, wherein said capture probe is or comprises a dT oligonucleotide or dU oligonucleotide.

34. The method of claim 1, wherein the first magnetic particulate solid support has a positive or negative surface charge.

35. The method of claim 1, further comprising contacting the sample with the first magnetic particulate solid support in the presence of a plurality of solid magnetic particles, wherein the plurality of first magnetic particulate solid supports and the plurality of solid magnetic particles are of different size.

36. The method of claim 15 or 23, further comprising lysing the sample in the presence of a plurality of magnetic solid particles capable of binding cells, wherein the plurality of magnetic solid particles and the first magnetic particulate solid support are of different size.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

Applicant has overcome the previous objection of claims 1-4, 13, 15, and 18, 21-24 and 34-36 in the office action of January 28, 2011 in view of the claim amendments.

Applicant has overcome the previous rejection of claims 1-25 and 34-36 under 35 USC First Paragraph in the office action of January 28, 2011 in view of the claim amendments.

Applicant has overcome the previous rejection of claims 1-25 and 34 under 35 U.S.C. § 103(a) as being unpatentable over Kleiber in view of Lubenow and further in view of Schubler in view of filing of the declaration and persuasive arguments made by the Applicant as discussed below.

Applicant has overcome the previous rejection of claims 35 and 36 under 35 U.S.C. § 103(a) as being unpatentable over Kleiber, Lubenow, Schubler and Petersen in view of filing of the declaration and persuasive arguments made by the Applicant.

Prior art considered: Haukanes et al (Nature Biotechnology, 1993, 11, pgs. 60-63).

Haukanes teaches a method for the isolation of nucleic acids and proteins separately using magnetic beads coated with affinity capture probes. Haukanes does not teach or make it obvious the combination of method steps of amended claim 1.

With regard to the art based rejection, Applicant has argued in the declaration that one of ordinary skill in the art would recognize that the method steps for isolating nucleic acids and proteins of Kleiber teaches away from the presently claimed invention. The arguments are persuasive (Declaration, pg. 3, Remarks, July 27, 2011, pgs. 8-10) and the rejection based on Kleiber has been withdrawn. Furthermore, Applicant has

further argued one having ordinary skill in the art would not have combined the teachings of Lubenow and Schubler with the method steps of Kleiber (Remarks of May 31, 2011, July 27, 2011, Declaration of July 27, 2011). The arguments are persuasive and therefore rejections based on Kleiber are withdrawn.

The art of the record taken individually or in combination do not teach or make it obvious the combination of method steps requiring the step of a sample not containing any chaotropic agent and contacting the sample with a first magnetic particulate solid support under conditions wherein nucleic acid components bind to the first magnetic particulate solid supports in a sequence independent manner and the protein components remain substantially intact; and simultaneously contacting the sample with a second magnetic particulate solid support distinct from the first magnetic particulate solid support, under conditions wherein protein components contained in the sample bind to the second magnetic particulate solid support through a chromatographic interaction and the nucleic acid components remain substantially intact; and separating the magnetic particles from the unbound sample. The novelty of the invention is the simultaneous isolation of intact nucleic acids and intact proteins from the same sample without the use of chaotropic agent.

Conclusion

Claims 1-25 and 34-36 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Narayan K. Bhat/
Examiner, Art Unit 1634

/Stephen Kapushoc/
Primary Examiner, Art Unit 1634